REMARKS

The present communication is responsive to the Official Action mailed January 4, 2011, rejecting all of the claims pending in the application ("Official Action"). In particular, the Examiner rejected claims 1-4, 6-16 and 18-24. Claims 1, 3-4, 6-9, 11, 13, 15-16, 18-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (2003/0015200) ("*Hansen*") in view of Kullik et al. (6,895,962) ("*Kullik*"). Claims 2 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Hansen* and *Kullik* as applied to claim 1 above, and further in view of Farrugia et al. (6,332,463) ("*Farrugia*"). Claims 10, 12, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Hansen* and *Kullik* as applied to claims 6, 11, 18 or 23 above, and further in view of Rapoport et al. (5,803,066) ("*Rapoport*").

Initially, Applicant wishes to thank the Examiner for withdrawing the prior rejection. However, Applicant respectfully disagrees with the new rejections. For at least the reasons recited herein, Applicant requests that the Examiner reconsider. Applicant submits that the application is in condition for allowance.

Claim Rejections - 35 U.S.C. §112

The Examiner has rejected independent claims 1 and 15 for omitting essential elements under 35 U.S.C. ¶112, second paragraph.[1] In this regard, the Examiner proposes that the

[1] The Office Action rejection of claim 1 and 15 is expressed as being based on § 112, second paragraph. (Office Action at 2.) However, Applicant is unaware of any precedent for rejecting claims for missing essential elements under § 112, second paragraph. Applicant is aware that such a rejection might be based on § 112, first paragraph and therefore presumes that the current rejection

"program to determine inspiratory/expiratory cycles" from the speed signal detected by the speed sensor as identified in dependent claims 6 and 12 is essential to claim 1. The Examiner also proposes that claim 15 has improperly omitted the speed sensor, control means and programs for determining cycles.

Applicant respectfully disagrees with the rejections. M.P.E.P. § 2172.01 identifies that elements missing from the claims might be required if the missing element is described by the applicant as being necessary to practice the invention in the specification.

With regard to claim 1 and the particularly claimed programs of dependent claims 6 and 12, Applicant respectfully reminds the Examiner that these features were originally filed as dependent claims and thus, were originally recognized as being optional features in the specification. Moreover, the Examiner has not pointed to any particular statement in the specification that identifies the purportedly missing element as being necessary to the invention of claim 1. In this regard, claim 1 already contains means of calculation being adapted to detect new inspiratory or expiratory cycles. (See, e.g., Applicant's Specification at p. 3, ll. 28-30 ("said means of calculation are capable of detecting new inspiration or expiration cycles, and to consequently adapt the level of the pressure 30 setting").) Moreover, although the Examiner has suggested a belief that the calculation means is merely for "determining" existence of such cycles, Applicant submits that the specification is consistent with the current "detect" language of claim 1. (Id.) As such, it is unclear why

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is intended to be based on of § 112, first paragraph. Appropriate clarification is requested in the event that the Examiner intends to maintain the rejection.

the Examiner believes essential elements are missing from claim 1. Applicant submits that claim 1 satisfies requirements of § 112.

With regard to claim 15, while Applicant disagrees with the assertions, Applicant has amended the claim to include the speed sensor and processor for purposes of expediting prosecution. (See, e.g., Applicant's specification, p. 7, ll. 19-28.)

For at least these reasons, Applicant respectfully requests that the Examiner withdraw the § 112, first paragraph rejections.

Claim Rejections - 35 U.S.C. §103

In the present Office Action, the Examiner has also rejected claim 1 as being obvious based on a combination of *Hansen* and *Kullik*. Essentially, the Examiner contends that all of the features of claim 1 are disclosed in the *Hansen* reference with the exception of the inertial aspects of the turbine. (Office Action at 4.) Applicant respectfully disagrees. In view of the rejection, there appears to be a misunderstanding of Applicant's technology. To this end, Applicant submits that the Office Action has not given due regard to the language of the claims as they would be understood in view of the specification, and in so doing, it is believed that a *prima facie* rejection of obviousness has not been presented.

Applicant's invention of claim 1 is a breathing assistance device. The device at least includes the following:

> a turbine to generate a flow of pressurised respiratory gas, said turbine having an inertia less than about 200 $g.cm^2$,
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> a duct adapted to carry the pressurised gas to a patient, and
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> control means for controlling gas pressure capable of computing a pressure setting for the turbine,

> wherein the turbine is connected to a speed sensor capable of acquiring a signal corresponding to a rotation speed of a rotating element of the turbine, and the control means includes means of calculation connected to said speed sensor to compute the pressure setting using only said speed signal and send the pressure setting to the turbine, said means of calculation being adapted to detect new inspiratory or expiratory cycles using only said speed signal, and consequently adapting a level of said pressure setting.

Applicant respectfully submits that *Hansen* does not teach or suggest all of these features nor do the references to *Kullik* make up the difference. In regard to the means of calculation to compute the pressure setting from the speed signal, the Examiner has relied on paragraphs 34 and 41-42. These paragraphs provide as follows:

> [0034] Also shown in FIG. 2 are the feedback and control components that determine the pressure in the ventilator and actuate the diverter valve 211 in response. The ventilator 200 therefore includes a control system 250 and a feedback sensor of some type. The control system 250 is capable of actuating the diverter valve 211 by sending an appropriate control signal to the actuator 212. In order to actuate the diverter valve 211, the control system 250 must be able to determine a switching time. The actuation may be done in response to a feedback signal generated by one or more feedback sensors. The feedback sensor may be a pressure or flow volume sensor 229 positioned on or between the diverter valve 211 and the mask 222. Alternatively, or in addition to sensor 229, one or more motor speed sensors 234 and 236, such as an electrical load sensor, an optical rotational speed sensor, a magnetic rotational speed sensor, a mechanical rotational speed sensor or the like, may be associated with corresponding gas supplies 204 and 206.
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> [...]

> [0041] In a third embodiment, one or more motor speed sensors 234 and 236 are used to control the diverter valve 211. In the two motor speed sensors embodiment, for example, the point in time when the motor speed of the positive relative pressure gas supply 204 drops, patient inhalation has stopped and exhalation has begun. As the positive pressure continues to be supplied, the pressure in the ventilator increases when the patient stops inhaling (i.e., an airflow backup occurs). This increase in pressure will cause the motor of the positive relative pressure gas supply 204 to slow down. Therefore, the control system 250 may now control the actuator 212 and move the diverter valve 211 to select the negative pressure port 305 and the negative relative pressure gas supply 206, or select a greater opening percentage for the negative pressure port 305.
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> [0042] Conversely, when the motor speed of the negative relative pressure gas supply 206 drops, as detected by the motor speed sensor 236, exhalation has stopped and inhalation has begun. The control system 250 may now control the actuator 212 and move the diverter valve 211 to select the positive pressure port 303 and the positive relative pressure gas supply 204, or select a greater opening percentage for the positive pressure port 303.

(*Hansen*, ¶¶ 34, 41-42.)

These paragraphs do not teach or suggest Applicant's technology. For example, there is no teaching or suggestion of a control means that computes the pressure setting using only said speed signal. Moreover, it does not teach that the control means sends the pressure setting to the turbine. In *Hansen*, two motors with impellers or fans are used and the settings of the motors are not adjusted. (See *Hansen* at ¶ 31 ("In this manner, using the two gas supplies 204 and 206, pressure regulation is achieved and the patient may be aided in breathing without having to change the speed of an associated blower. This extends motor life, creates less noise, and allows lower motor running temperatures.").) To

adapt the pressure level produced by these two blowers of *Hansen* apparatus, the controller of *Hansen* merely switches the position of a diverter valve to the flow produced by one or the other of the two fans. (See, e.g., *Hansen* at ¶ 41.) Thus, to the extent that a speed signal is involved, *Hansen* merely detects a speed change and switches the diverter control rather than computing a pressure setting and sending it to a turbine. (See, e.g., *Hansen* at ¶ 41-42).

For at least these reasons, Applicant submits that claim 1 is in condition for allowance. A *prima facie* rejection of obviousness has not been presented since all of the features of Applicant's invention have not been cited in the prior art. Accordingly, Applicant requests that the Examiner withdraw the rejection of claim 1. Moreover, the rejection may also be withdrawn for independent claim 15, which may be compared with the subject matter of claim 1. Finally, Applicant requests that the Examiner allow their dependent claims, which include additional allowable subject matter further to the allowable subject matter of the independent claims.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant’s attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: April 12, 2011

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